Remarks

Claims 1-5, 7-11 and 13-22 are in the case.

Claims 6 and 12 were previously canceled.

Claims 1-5, 7-11 and 13-16 are not amended herewith.

Claims 17-22 are new claims. Basis for Claims 17 and 18 is submitted to be found in the application as filed at 8/20-9/3 taken with 9/21 and 10/1. The limits of new claims 19 and 20 are the same as those in Claims 10 and 13 respectively. It is submitted that the subject matter of Claims 21 and 22 would be understood as standard operating procedure by those skilled in the art.

We turn now to the rejections.

Claims 10-11 and 13-16 are rejected under 35 U.S.C. 112, first paragraph on the basis that H_2S is an asphyxiant gas and is counterindicated for pulmonary disorders "in the absence of further limiting features".

Reconsideration of this rejection is requested.

Turning firstly to the characterization in the office action of H_2S as being an asphyxiant gas, this characterization is overgeneralization in the context here. H_2S is not an asphyxiant gas when administered at a dosage of 0.1 to 100 ppm in nitrogen (Claim 10) or in a therapeutically effective amount for treating a pulmonary disorder which is not asthma and which is associated with depletion of the S-nitrosoglutathione pool in the lung or depletion of the glutathione pool in the lung or production of reactive oxygen species in the lung (Claim 14).

Turning now to the merits, in the previous response, it was contended that the rejection is one under 35 U.S.C. 112, for lack of utility, and in accordance with MPEP Section

2164.07(I)(B), the burden is on the examiner to show that one of ordinary skill in the art would reasonably doubt the asserted utility; this contention is not contested in the office action.

We turn now to Claims 14-16 and presumably also the new Claims 18-20 and 22 These claims relate to treating a pulmonary disorder which is not asthma.

Claims 14-16, 18 and 22 require a therapeutically effective amount of agent which embraces or comprises H_2S, that is an amount which provides remedial effect, thereby excluding an amount which causes more harm than benefit. New Claim 19 further defines a dosage for H_2S of 0.1 to 100 ppm in nitrogen and Claim 20 further defines a dosage for H_2S of 0.1 to 10 ppm in nitrogen. Consider further that so far as Claims 19 and 20 are concerned, the H_2S is administered in nitrogen and would be understood by those skilled in the art to be administered while the patient would be breathing air and that the air would reduce the concentration of the H_2S in the lungs from the recited ppm H_2S and would less likely oxidize, e.g. to sulfuric acid, when administered in nitrogen compared to when administered in air.

Now consider whether the PTO has met its burden for showing inoperativity. Since asthma is excluded from treatment of Claims 14-16 and 18-20 and 22, the only evidence that is asserted in the office action that is directed to Claims 14-16 and 18-20 and 22 is newly cited TOXCENTER, STN ONLINE, Accession No. 2002:618658 which in relation to levels of H_2S of 100 ppm and less, reports definitely only the detriments of eye irritation after several hours of exposure at 100 to 1000 ppm H_2S and fatigue believed by some to be a consequence of intermittent exposure to 50 to 100 ppm H_2S and refers to some reports of the threshold for eye irritation occurring after several hours of exposure to 10.5 to 21.0 ppm H_2S, apparently in relation to healthy individuals.

It is submitted that the TOXCENTER publication clearly allows for determination of a therapeutic amount (Claims 14-16 and 18 and 22) especially given the guidelines in the application for H_2S dosage at page 10, lines 1 and 2 and page 12, lines 8-12 and does not negate the enablement or operativity of new Claims 19 and 20 which state definite concentration ranges for H_2S administration. The eye irritation and fatigue indicated in the TOXCENTER document do not disprove or detract from there being therapeutic effect for treating the pulmonary disorders different from asthma as claimed in Claims 14-16, and 18-20 and 22.

We turn now to Claims 10, 11, 13 and 21 which are directed to administering agent comprising H_2S where the H_2S is administered at a dosage of 0.1 to 100 ppm in nitrogen (Claims 10 and 11) or of 0.1 to 10 ppm in nitrogen (Claim 13) to treat pulmonary disorders as described in Claim 10 where asthma is not excluded.

The documents relied on in the office action as evidence of inoperativeness for H_2S treatment of asthma are Embase abstract Accession No. 2000083448 (2000), Chemical Abstracts 115:56107 (1991) and Medline Abstract Accession No. 92296647 (1992). The only definite statistically significant data in any of these shows that 2 of 10 asthmatic subjects experienced bronchial obstruction on exposure to 2 ppm H_2S for 30 minutes in an exposure chamber.

This evidence is submitted to be inadequate to rebut enablement and utility and is submitted to be consistent with the invention because it is consistent with discontinuing H_2S treatment in those few cases where H_2S treatment would be a problem, as is conventional generally in medical treatments where the treatment is discontinued if a problem arises because of the treatment. See pages 4 and 5 of the response of December 27, 2002. This position on the part of applicant has not been rebutted or contested. New Claims 21 and 22 are explicitly

pertinent to this position.

We turn now to the other rejection, namely rejection of Claims 1-3, 7-9 and 14-15 under 35 U.S.C. 112 on the basis that the specification does not provide enablement for the treating agents not specifically disclosed, i.e., does not provide enablement for "agent which causes repletion or increase of the S-nitrosoglutathione pool in the lung or protects against toxicity where glutathione is depleted in the lung or where reactive oxygen species are increased in the lung and does so independently of reaction with oxygen."

Reconsideration is requested.

For this rejection, the burden is on the PTO to prove that one skilled in the art would not be able to conceive of other treating agents given applicant's disclosure where a test for determining treating agent is set forth in the disclosure in the application as filed at page 5, lines 15-20 and substantial guidance is given on treating agents in the application at page 8, line 20 - page 10, line 2, and in the working example. It is not sufficient for the office action simply to say that other treating agents cannot be determined without undue experimentation. See In re Dinh-Nguyen, 181 U.S.P.Q. 46, 47 (CCPA 1974); In re Gardner 177 U.S.P.Q. 396, 397 (CCPA 1973); and Ex parte Reese, 40 U.S.P.Q. 2d 1221 (Bd. App. 1996), copy of decision enclosed. The rejection is defective because the PTO has not met its burden.

The office action compares the present case to "method of curing AIDS by administering agent that kills the virus that causes AIDS." The comparison is submitted to be defective. Here an *in vivo* test is given at page 5 of the disclosure which would allow determination of effective agent based on experience. The killing of the AIDS virus *in vivo* presumably would be a treatment for AIDS. In any event, Claims 1 and 15 name particular diseases and a test for

determining treating agent is set forth in the disclosure at page 5. The reason that the various pulmonary disorders are effectively treated by agent as recited because a common source of symptomology is present in the description of mechanism therefor, i.e., since the diseases are related by the same mechanism, they all are logically treated by a protocol which affects that mechanism.

It is noted that new Claims 17 and 18 were drafted to comply with what the office action indicates would be sufficient to describe treating agent.

Allowance is requested.

Respectfully submitted,

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